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**From:** CN=Alana Lee/OU=R9/O=USEPA/C=US

**Sent:** Thur 5/31/2012 3:55:57 PM

**Subject:** Inside EPA: EPA Weighs First-Time Short-Term Cleanup Limit For TCE, Worrying Industry - May 30, 2012

**MAIL\_RECEIVED:** Thur 5/31/2012 3:55:58 PM

[In a recent letter](#)

[a white paper](#)

[Region IX officials recommended](#)

[its paper](#)

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<http://insideepa.com/201205302400361/EPA-Daily-News/Daily-News/epa-weighs-first-time-short-term-cleanup-limit-for-tce-worrying-industry/menu-id-95.html>

## Daily News

### EPA Weighs First-Time Short-Term Cleanup Limit For TCE, Worrying Industry

Posted: May 30, 2012

Top EPA officials are weighing a first-time regulatory limit to prevent cardiac birth defects and other harms due to acute inhalation exposures to the ubiquitous solvent trichloroethylene (TCE), a move that is worrying industry officials who say the science is too uncertain, the method for crafting the limit is at odds with agency policy and the limit is orders of magnitude stricter than similar levels crafted by other agencies.

At the request of both industry groups and staff in EPA Region IX, officials in the Office of Solid Waste and Emergency Response (OSWER) and the Office of Research and Development (ORD) are reviewing a plan by regional staff who have proposed an interim Removal Action Level (RAL) for addressing TCE contamination at the Middlefield-Ellis-Whisman (MEW) Superfund site, in Mountain View, CA of 15 micrograms per cubic meter ( $\mu\text{g}/\text{m}^3$ ).

The limit is based on EPA's recently finalized Integrated Risk Information System (IRIS) assessment for TCE, which set a reference concentration (RfC) --or the amount of the substance EPA anticipates can be inhaled daily over a lifetime without causing adverse health effects -- of 2  $\mu\text{g}/\text{m}^3$ . While several peer review panels recommended that EPA rely on a 2003 study, led by Prof. Paula D. Johnson, as its principal study showing cardiac birth defects from TCE exposure, industry says the science is too uncertain to be used for regulatory purposes.

In a recent letter to deputy EPA waste chief Barry Breen, industry groups that may be subject to the proposed limit called on headquarters officials to conduct a weight-of-evidence evaluation to determine the scientific validity of Region IX's proposed RAL.

"Given the importance of accurate and responsible risk management communications regarding TCE, we respectfully request that EPA, at the Headquarters level, conduct a thorough analysis of the available literature regarding the potential developmental effects of TCE and make a formal determination based on the weight of the scientific evidence," according to attorneys for Raytheon Company and Schlumberger Technology Corp., which are responsible for remediating TCE contamination at the MEW site.

The industry letter to Breen was accompanied by a white paper prepared by consultants for the companies that warned that the proposed RAL would impose "substantial practical implementation issues for monitoring and managing TCE exposures. It may also result in unwarranted alarm among potentially exposed individuals and would be expected to result in significant confusion, given the orders of magnitude difference between the proposed RAL and other regulatory standards and screening levels for TCE."

One source familiar with the issue says that the industry concern may be driven by fears that Region IX's proposed interim RAL, which it crafted to protect construction workers at or near the MEW site, may open the door to strict new cleanup requirements and bolster future personal injury and worker protection claims that might be brought against private and federal responsible parties at the hundreds of sites nationwide where the chemical is present. "This opens the door for acute exposure standards many times more stringent than what was done before," the source says.

The industry concern in this case highlights broader fears that new EPA risk estimates will drive stricter regulatory requirements.

Environmentalists, meanwhile, are urging EPA headquarters to back Region IX's proposal. The Center for Public Environmental Oversight (CPEO) recently forwarded to EPA waste chief Mathy Stanislaus a memo developed by the center's consultant recommending agency-wide adoption of the Region IX proposal. "We are always concerned when Responsible Parties inject themselves into toxicological debates because, to our knowledge, they never argue for more protective standards," Lenny Siegel, CPEO's executive director, said in a May 29 cover letter. An agency spokeswoman says EPA's Office of Solid Waste and Emergency Response, in consultation with EPA's Office of Research and Development, is reviewing Region IX's proposed RAL. "At this time, we do not have an estimate as to when that review will be completed," she said.

#### Responsible Parties

Earlier this year, Region IX officials recommended that responsible parties and others at or near the MEW site consider the RAL in their air, soil and other sampling plans at the site, where work is planned to build commercial buildings and offices for lessees, including internet giant Google, Inc. and others.

Spokesmen for Google and others involved in the dispute did not return requests for comment.

Of particular concern are plans to drill through concrete slabs for utility pathways, which regulators fear will increase exposure to TCE vapors from contamination in subsurface soil and groundwater. Such exposure pathways,

known as vapor intrusion, occur when contaminants in groundwater and soil break down and travel as vapors into crawlspaces and basements of nearby buildings.

EPA is currently developing guidance on assessing and mitigating the effects of vapor intrusion from chlorinated solvents and petroleum hydrocarbons and is also planning a rule to allow regulators to list contaminated sites on the Superfund National Priorities List based solely on the presence of vapor intrusion.

EPA says its upcoming rule adding vapor intrusion as a basis for listing sites on the NPL is likely to reprioritize its cleanup program toward those sites because they may pose a higher risk than other sites without such pathways. According to the industry white paper, Region IX derived its proposed RAL by multiplying the RfC of 2 ug/m<sup>3</sup> by the ratio of chronic exposure, or 24 hours a day, to short-term exposure, or 10 hours a day that workers at the site were likely to experience. The resulting site specific RfC of 4.8 was rounded up to 5, and then multiplied by a hazard quotient of 3, as per OSWER's 2008 policy memo for calculating RALs.

The proposed RAL of 15 ug/m<sup>3</sup> is intended protect workers who are on a construction site for 10 hours per day. In addition to proposing an interim RAL for short-term exposure, Region 9 is recommending TCE monitoring guidelines and mitigation efforts like ventilating buildings during the workday.

"In light of [the IRIS assessment] and as a matter of good construction practice, EPA recommends that you take this interim removal action level into account and that the buildings be maximally ventilated while workers are inside the building and subsurface conduits remain open to ensure that workers are protected from Site contaminants. EPA also recommends that the Sampling Plan include monitoring for TCE in air and contingency measures if the interim removal action level is exceeded while subsurface conduits remain open and there is potential exposure to workers."

#### Lifetime Exposure

However, the two companies are challenging the proposed RAL. Their April 17 white paper, prepared by Exponent and Geosyntec consultants, says by creating a short-term RAL from an RfC intended for continuous lifetime exposure, Region 9 is considering an overly strict standard and will cause unnecessary precautions and alarm.

"Although the EPA RfC of 2 ug/m<sup>3</sup> was developed for continuous exposure as a lifetime average concentration, Region 9 has been considering applying the RAL as a daily average concentration," the report states. "The RAL assumes that developmental effects could be produced by a single day of exposure to TCE by a pregnant female, and thus, the RAL is applied to short-duration exposures. The underlying IRIS documentation for the RfC, however does not indicate that it should be applied to anything other than chronic exposure."

The industry paper also challenges EPA efforts to limit potential cardiac birth defects, saying evidence of such a link is tenuous because of contradictory findings and scientific studies with flawed methodologies. In particular, the industry groups is challenging EPA's reliance on the Johnson study, reprising a dispute that also plagued development of the IRIS assessment. "While there is potentially suggestive evidence of a causal association between TCE and developmental effects, the evidence is weak; it includes contradictory findings, and some of the key studies have fundamental methodological flaws," the paper says.

Finally, the industry paper charges that the proposed RAL is orders of magnitude stricter than other limits set by other regulatory and public health agencies. For example, the paper notes that the short-term exposure limit for TCE recommended by the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (AEGGL) is 410,000 ug/m<sup>3</sup>, which is a threshold exposure limit for emergency exposures of 10 minutes to 8 hours.

But the environmentalists' consultant, PM Strauss and Associates, says in its paper that Region IX's proposal is an appropriate response to the new IRIS assessment for TCE.

The consultant acknowledges IRIS reviews are generally used to create RALs for chronic exposure, and that EPA guidance on RALs also indicates they are usually for long-term exposure.

But in this case, the consultant writes, a short-term RAL for TCE exposure is appropriate, if the science holds true, because of the potential risk of birth defects. While other non-cancer risks of TCE exposure -- kidney, neurological and immunological effects -- occur with chronic exposure, birth defects occur during a 21-day window in the first trimester of pregnancy, according to the consultant's memo.

"The RfC of 2 ug/m<sup>3</sup> is based in part on critical heart malformations," the memo states. "It does not appear that this warrants further analysis except when new information is developed." Also, the consultant says that even though the industry white paper cites several studies suggesting weaker short-term exposure limits, the consultant calls those values "out of date and unprotective."

Region IX's effort to protect workers with a short-term RAL, the memo says, shows what's missing from the IRIS

assessment of TCE, namely how the revised toxicity should be applied to practical situations, which in this case is on an interim basis with exposure limited to 10 hours a day.

“Region IX’s attempt to develop an interim RAL as construction on contaminated land is taking place is a practical response to protecting the public,” the memo states. “There needs to be a point EPA at which can recommend that short-term contamination is too high, and one must take measures to prevent this.” -- Dave Reynolds  
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